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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/414,384	10/07/1999	ANDREW CLARK	0037.00	3236

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EXAMINER
LEWIS, AARON J

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/414,384	Applicant(s) ANDREW CLARK ET AL.
	Examiner AARON J. LEWIS	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 28, 2001*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-35* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (EP 0 808 635 A2).

As to claim 21, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphram having a particular flexibility in combination with dimensions of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance.

As to claims 22-25, Howlett, as discussed above with respect to the particular quantity of flow resistance the particular quantity of flow rate can be arrived at through mere routine obvious

experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

As to claims 26 and 27, the particular period of time during which the flow resistance is applied by the device of Howlett will vary with the manner of use of the device. That is, the duration of time during which flow resistance is applied is directly proportional to the duration of a particular patient's inhalation period. Consequently, this time period can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular time period.

As to claims 28 and 29, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphram having a particular flexibility in combination with dimensions of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance. As to the claimed flow rate, the particular quantity of flow resistance and therefore the particular quantity of flow rate can be arrived at through mere

routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

Claims 30 and 31 are substantially equivalent in scope to claims 22 and 26 respectively, and are included in Howlett for the reasons discussed above with respect to claims 22 and 26.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Howlett (EP 0 808 635 A2).

As to claim 32, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator to provide a first flow rate and subsequently provides a second flow resistance to provide a second flow rate.

5. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (EP 0 808 635 A2).

Claims 33-35 are substantially equivalent in scope to claims 26,24,25 respectively, and are included in Howlett for the reasons set forth above with respect to claims 26,24 and 25.

Response to Arguments

6. Applicant's arguments filed 09/28/2001 have been fully considered but they are not persuasive.

Applicant's assertion that Howlett lacks a flow resistance modulator which provides a high flow resistance is disagreed with because the enlarged illustrations of figs.2-4 each show a flow resistance modulator which is intended to control the flow rate of air through the inhaler during patient inhalation. If a patient inhales too forcifully, the flow resistance modulator (figs.2-4) begins to close off some or all of the air inlets to the inhaler in dependence upon the degree of forcefullness of such an inhalation and in dependence upon the physical design parameters of the flow resistance modulator. This relates to the claims of the instant application as follows: the arrangements of figs.2-4 of Howlett show a flow resistance modulator which acts to restricts a patient's inhaled flow when it (inhaled flow) exceeds a predetermined threshold thereby providing a high flow resistance and subsequently relaxes if and when such a patient's inhaled flow rate decreases to a level which is beneath the predetermined threshold for restricting the flow thereby subsequently providing a lower flow resistance.

Applicant's arguments regarding an alleged lack of motivation for altering the flow resistance modulator (figs.2-4) of Howlett to achieve particular desired flow resistance/rates is disagreed with because of the disclosure by Howlett (col.3, lines 46-50) which addresses how (e.g. by adjustment of diaphram flexibility) one of ordinary skill might make a device which would achieve control of inhaled flow rates of 30-60 liters per minute. Therefore, it would have been obvious to

modify the diaphram flexibility to achieve the particular inhaled flow rate(s) desired by a given patient. Such an adjustment would have been necessary in the case in which a child is using the device rather than an adult or when a patient of less than average breath capacity is using the device or even when a patient subject to asthma attacks is using the device.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis; December 3, 2001

Aaron J. Lewis
Primary Examiner